UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE
SECRETARY

REQUEST REPLY BY: 4/11

Approved with attached comments and edits.

Richard A. Meserve 4/10/02

March 28, 2002

COMSECY-02-0014

MEMORANDUM TO: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

FROM: Annette L. Vietti-Cook, Secretary

SUBJECT: RE-AFFIRMATION OF THE FINAL RULE ON PART 35 -- MEDICAL USE OF BYPRODUCT MATERIAL

The final rule on Medical Use of Byproduct Material (Part 35) was affirmed by the Commission on October 23, 2000. Publication of the final rule has been delayed based on direction from Congress not to implement or enforce certain parts of the rule until after the NRC submitted a report to Congress explaining why the regulatory burden associated with the rule could not be reduced further without adversely affecting the public health and safety. The NRC submitted the report to Congress on February 11, 2002. Subsequently, as briefed to the Technical Assistants, the staff is recommending that the final rule be revised to include Subpart J, Training and Experience Requirements, as was included in the proposed rule.

The pages of the *Federal Register* notice (FRN) which contain the major changes to the Statement of Consideration and the Final Rule are attached. The remaining pages of the FRN are available in SECY and will be provided if requested. Additional conforming changes have been made throughout the FRN.

The Commission is requested to vote on the attached revision to Part 35. Once all votes are received, an affirmation session will be scheduled for the Commission to re-affirm the final rule prior to publication.

Attachment: Changes to the FRN on the Final Rule on Part 35

cc: EDO
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CHAIRMAN MESERVE'S COMMENTS ON COMSECY-02-0014

COMSECY-02-0014 proposed changes to the Statement of Consideration and the final rule on Medical Use of Byproduct Materials (Part 35). The changes are prompted by comments by the ACMUI concerning conflicts between the training and experience (T&E) requirements in the rule and existing certification practice for some boards (e.g., medical physicists and radiation safety officers). The ACMUI indicated that the conflicts would marginalize some boards and lead to a shortage of qualified medical personnel.

In response to this concern, the current Subpart J has been inserted into the final rule to allow a two-year transition period. I support this approach because: (1) it is consistent with the T&E provisions in the proposed rule that were published for public comment, and, therefore, there is no need to seek further comment; (2) it would allow those boards which have already developed changes in their board certification reflecting the revised T&E requirements to proceed with implementation of those changes; and (3) it provides time for the staff to work with the ACMUI and the medical community in resolving any concerns with the revised T&E requirements during the transition period. All Commissioners have agreed that the staff should continue to work with the ACMUI and the medical community to resolve any outstanding concerns about the T&E requirements.

This effort should lead to a SECY paper that will discuss various options for addressing the T&E issue before the revised final rule becomes effective, i.e., within 6 months after publication of the final rule. This paper should allow for Commission deliberation of the recommended changes, allow time for public comment on any proposed changes, and the implementation of any final changes to Part 35, if necessary, within the two-year transition period.

To appropriately reflect the above approach, the redlined paragraph on p.44 and p.323-324 should read:

"The NRC believes that Subpart J should be retained for a 2-year transition period as stated in the proposed rule (63 FR 43516: August 13, 1998). The issue of recognition of medical and other specialty boards was discussed during an ACMUI briefing of the Commission on February 19, 2002. In that meeting, two committee members expressed concern that some boards did not qualify for recognition and may not be ready for recognition within 6 months after publication of the final rule. Therefore, implementation of the new Part 35, without Subpart J, could disrupt the current license authorization process for new medical personnel, and might cause shortages of authorized medical personnel, because many license authorizations are granted based on recognition of board certification. The Commission has considered this matter, and decided to retain the current training requirements in Subpart J for a 2-year period after publication of the final rule, as stated in the proposed rule published on August 13, 1998. As stated in Section IX, Implementation, during that 2-year period, licensees will have the option of meeting either the requirements of Subpart J or the requirements in Subpart B and D-H. During this transition period, the NRC will continue working with the ACMUI and the medical community to resolve any concerns with the T&E requirements. The Commission will consider changes to the training and experience requirements, as appropriate. ~~The NRC states that licensees will have the option of complying with either Subpart J or Subparts B and D-H, and that Subpart J will be deleted after the 2-year period.~~"

The first redlined paragraph on p.494 should read:

" Subpart J, Training and Experience Requirements, is in the current Part 35 and will be retained for 2 years. Licensees will have the option to comply with the training and experience requirements in this subpart or in Subparts B and D-H until 2 years after the final rule is published in the Federal Register. ~~At that time, this subpart will be deleted~~. During this transition period, the NRC will continue working with the ACMUI and the medical community to resolve any concerns with the T&E requirements. The Commission will consider changes to the training and experience requirements, as appropriate. A more detailed discussion of the Commission's changes to the training and experience requirements is in Section III of the SUPPLEMENTARY INFORMATION section of this document. The schedule for implementation of the training and experience requirements is in Section IX of the SUPPLEMENTARY INFORMATION section of this document."

The redlined paragraph on p.528-529 should read:

"The issue of recognition of medical and other specialty boards was again discussed during an ACMUI briefing of the Commission on February 19, 2002. In that meeting, two committee members expressed concern that some boards did not qualify for recognition and may not be ready for recognition within 6 months after publication of the final rule. Therefore, implementation of the new Part 35, without Subpart J, could disrupt the current license authorization process for new medical personnel, and might cause shortages of authorized medical personnel, because many license authorizations are granted based on recognition of board certification. The Commission has considered this matter, and decided to retain the current training requirements in Subpart J for a 2-year period after publication of the final rule, as stated in the proposed rule published on August 13, 1998. As discussed, under Section IX, Implementation, licensees will have the option of complying with Subpart J or Subparts B and

D-H for 2 years~~, and Subpart J will be deleted after the 2-year period~~. During this transition period, the NRC will continue working with the ACMUI and the medical community to resolve any concerns with the T&E requirements. The Commission will consider changes to the training and experience requirements, as appropriate."

Corrections to Comsecy-02-0014 Paper - page 16

PRM-35-16

On January 11,2002, the NRC docketed a January 3, 2001, letter from Donald A. Podoloff, MD, of the American College of Nuclear Physicians, and Jonathan M. Links, PhD, of the Society of Nuclear Medicine, to the Office of the Secretary, as a petition for rulemaking under 10 CFR 2.802 (PRM-35-16). The petitioners requested that the Commission: rescind its approval of the NRC staff's proposed revision to 10 CFR ~~p~~Part 35, "Medical Use of Byproduct Material"; revoke all of 10 CFR ~~p~~Part 35, except for specifically identified requirements; and institute a new rulemaking proceeding to adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine that reflects the discipline's "unparalleled and undisputed safety record."

OFFICE OF THE SECRETARY

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March 28, 2002

Approved, subject to attached edits and the edits proposed by Commissioner McGaffigan.

Greta Joy Dicus 04/09 /02

COMSECY-02-0014

MEMORANDUM TO: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

FROM: Annette L. Vietti-Cook, Secretary

SUBJECT: RE-AFFIRMATION OF THE FINAL RULE ON PART 35 -- MEDICAL USE OF BYPRODUCT MATERIAL

The final rule on Medical Use of Byproduct Material (Part 35) was affirmed by the Commission on October 23, 2000. Publication of the final rule has been delayed based on direction from Congress not to implement or enforce certain parts of the rule until after the NRC submitted a report to Congress explaining why the regulatory burden associated with the rule could not be reduced further without adversely affecting the public health and safety. The NRC submitted the report to Congress on February 11, 2002. Subsequently, as briefed to the Technical Assistants, the staff is recommending that the final rule be revised to include Subpart J, Training and Experience Requirements, as was included in the proposed rule.

The pages of the *Federal Register* notice (FRN) which contain the major changes to the Statement of Consideration and the Final Rule are attached. The remaining pages of the FRN are available in SECY and will be provided if requested. Additional conforming changes have been made throughout the FRN.

The Commission is requested to vote on the attached revision to Part 35. Once all votes are received, an affirmation session will be scheduled for the Commission to re-affirm the final rule prior to publication.

Attachment: Changes to the FRN on the Final Rule on Part 35

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granted based on recognition of board certification. The Commission has considered this matter, and decided to retain the current training requirements in Subpart J for a 2-year period after publication of the final rule, as stated in the proposed rule published on August 13, 1998. As stated in Section IX, Implementation, during that 2-year period, licensees will have the option of meeting either the requirements of Subpart J or the requirements in Subparts B and D-H. The NRC states that licensees will have the option of complying with either Subpart J or Subparts B and D-H, and that Subpart J will be deleted after the 2-year period.

Individuals who have status as AUs, AMPs, ANPs, and RSOs at the time the rule becomes effective will be "grandfathered" under § 35.57, and will not have to satisfy the new training and experience requirements. For additional information on the "deemed status" of individuals when the final rule becomes effective refer to the general discussion of the training and experience requirements at the beginning of this section.

Issue 2: Why were the lists of certifying medical boards in Subpart J of the current Part 35 not updated during the rulemaking to include other medical specialty boards and other subspecialties?

Comment. Several commenters noted that there are other medical specialty boards and other subspecialties that should be added to the lists of certifying boards in Subpart J.

Response. The suggested updates were not made in the final rule because Subpart J ~~was~~ will be deleted 2 years after publication of the final rule and there are no lists of certifying specialty boards in the new training and experience requirements in Subparts B and D through

~~D through H when the rule becomes effective on [insert date 6 months from publication of the final rule]. All commercial nuclear pharmacy licensees (10 CFR 32.72 licensees) will have to comply with the new training and experience requirements for ANPs in §§ 35.55 and 35.59.~~

The NRC believes that Subpart J should be retained for a 2-year transition period as stated in the proposed rule (63 FR 43516; August 13, 1998). The issue of recognition of medical and other specialty boards was discussed during an ACMUI briefing of the Commission on February 19, 2002. In that meeting, two committee members expressed concern that some boards did not qualify for recognition and may not be ready for recognition within 6 months after publication of the final rule. Therefore, implementation of the new Part 35, without Subpart J, could disrupt the current license authorization process for new medical personnel, and might cause shortages of authorized medical personnel, because many license authorizations are granted based on recognition of board certification. The Commission has considered this matter, and decided to retain the current training requirements in Subpart J for a 2-year period after publication of the final rule, as stated in the proposed rule published on August 13, 1998. As stated in Section IX, Implementation, during that 2-year period, licensees will have the option of meeting either the requirements of Subpart J or the requirements in Subparts B and D-H. ~~The NRC states that licensees will have the option of complying with either Subpart J or Subparts B and D-H, and that Subpart J will be deleted after the 2-year period.~~

gjd 04-09-02

Delete (repeat)

The training and experience requirements in Subparts B and D through H of the final rule provide alternative pathways for individuals who are not board certified, i.e., the rule specifies the total number of hours of training and experience needed to become an AMP, ANP, AU, or RSO. This was done because we do not believe that we should require that individuals

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Approve subject to attached comments.

Nils J. Diaz 4/11/02

COMSECY-02-0014

MEMORANDUM TO: Chairman Meserve
Commissioner Dicus
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Commissioner Merrifield

FROM: Annette L. Vietti-Cook, Secretary

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COMMENTS OF COMMISSIONER DIAZ ON COMSECY-02-0014

General Comments

I approve, subject to my comments below, revision of the final rule for Part 35 to include Subpart J, Training and Experience Requirements, as was included in the proposed rule. I am also supportive of staff's generic statement in the FRN that recognizes that future changes to Part 35 are possible as experience with the new rule is gained by both the NRC and our licensees. This statement would cover any possible changes, including changes in the revised training and experience requirements, that might need to be made in our medical use regulations. Based on the agency's past experience, implementation of major revisions of our regulations (e.g., Part 20) often results in identification of additional changes that need to be made in the regulations.

I do not believe that the FRN should include a statement that notes that NRC is specifically reviewing the revised training and experience requirements. I believe that the boards will stop their review process if the FRN includes a statement that notes that NRC is specifically reviewing the revised training and experience requirements. I am supportive of the ACMUI and staff working to resolve specific concerns that have been raised regarding the revised training and experience requirements. I am also supportive of those boards that have already reviewed and revised, as necessary, their board certification requirements to meet the revised Part 35 requirements that were developed to ensure the safe use and handling of radioactive material.

Specific Comments

Page 11, paragraph 2, line 5

Insert text before the last sentence that notes the availability of the revised draft NUREG-1556, Volume 9, for comment because the FRN for the final rule will be published during the public comment period for the NUREG. This is another opportunity to make stakeholders aware of the fact that the guidance document is available for public comment.

Page 11, paragraph 2, line 7

Revise the last sentence to read "... is gained by both the NRC and our licensees." This change would make the statement more consistent with earlier public statements.

Page 44, second paragraph, line 2

As written, it appears that Subpart J was primarily retained for 2 years because of the concerns raised at the February 2002 ACMUI meeting. Add a statement before the second sentence that reflects the rationale in the proposed rule for retaining Subpart J, e.g., allow time for the medical specialty boards to revise, if necessary, their board certification requirements to reflect the revised training and experience requirements and to submit their applications for recognition to NRC, allow time for NRC to review and approve certification of the specialty boards, etc.

Page 44, second paragraph, line 5

Revise the sentence to read "... may not be ready to apply for recognition ..."

Page 44, second paragraph, lines 7-8

Revise the sentence to read " ... medical personnel~~, and might cause shortages of authorized medical personnel,~~ because ... ." There is already a national shortage of medical personnel, in general, and, at this time, I am unaware of any data to substantiate the claim that the revised Part 35 "might cause shortages of authorized medical personnel."

Page 44, second paragraph, line 13

Revise the sentence to read "... option of complying with ~~meeting~~ either the requirements ...."

Page 44, second paragraph, last sentence

Delete the last sentence because it is repetitive of the previous sentence.

Page 203, Issue 2.

Delete Issue 2 to be consistent with the format for the rest of this section of the FRN.

Page 323, last paragraph

See the comments on page 44, second paragraph

Page 326, response to Issue 1

The remaining sentence does not directly address the comments. Revise the response to read "We agree with the commenters that this section can be deleted (two years after publication of the final rule) because the requirements in § 35.57 for an experienced nuclear pharmacist are adequate. Therefore, this section ..."

Page 495, paragraph 1, line 2

Revise the second sentence to read "One change has been ~~was~~ made ..."

Page 499, last paragraph

Revise the sentence to read "...was not ~~be~~ changed."

Page 528, last paragraph, lines 6-7

Revise the sentence to read " ... medical personnel~~, and might cause shortages of authorized medical personnel,~~ because ... ."

Page 528, last paragraph

Add text to note availability of the transcript for the February 2002 ACMUI meeting, as noted for the earlier ACMUI meeting.

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March 28, 2002

Approved with attached comments and edits.
4/5/02
Edward McGaffigan, Jr.

COMSECY-02-0014

MEMORANDUM TO: Chairman Meserve
Commissioner Dicus
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Commissioner Merrifield

FROM: Annette L. Vietti-Cook, Secretary

SUBJECT: RE-AFFIRMATION OF THE FINAL RULE ON PART 35 -- MEDICAL USE OF BYPRODUCT MATERIAL

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COMMISSIONER MCGAFFIGAN'S COMMENTS ON COMSECY-02-0014

I approve the staff's revisions to Part 35, as provided in COMSECY-02-0014, subject to the attached changes. In particular, I approve that the final rule be revised to include Subpart J, Training and Experience Requirements, as was included in the proposed rule.

In the February 19, 2002 Commission Meeting with the Advisory Committee on the Medical Use of Isotopes (ACMUI), members of our advisory committee raised concerns about the training and experience requirements in the final Part 35. At that meeting, the Commission was told that implementation of the final Part 35 training and experience requirements would "marginalize" board certification and lead to unintended consequences. The staff's proposed solution (which I approve) is to return to the text of the proposed rule, allowing a 2-year implementation period when both sets of training and experience requirements would be acceptable. Concurrently, the ACMUI has formed a subcommittee to address the training and experience issues, and the subcommittee's goal is to recommend solutions to resolve the training and experience problems. Those eventual solutions may involve rulemaking, and I indicated in the ACMUI Commission meeting that I would try to work with the advisory committee on this issue.

The eventual solution to the training and experience problem, raised by the ACMUI, could involve rulemaking. We have told Congress that "consideration of future rule changes will remain possible,"[1] and we have publicly stated, "As experience is gained by both the NRC and our licensees, we remain open to future rule changes."[2] The staff's proposed language is silent on possible future rulemaking, implying that the 2-year period only provides additional time for the certification boards to modify their systems. In fact, during this 2-year time period, the ACMUI subcommittee will be developing alternatives to address the training and experience problem, the staff should provide the Commission with options for resolving the training and experience concerns raised by the ACMUI members, and the Commission will consider those options (including possible rulemaking). The Statements of Consideration should more accurately reflect that the Commission will consider other alternatives during the 2-year period.

The staff should add the following text to pages 44, 324, and 494 of the Statements of Consideration, as part of the staff's discussion of the 2-year transition period, and make similar changes throughout the rest of the Statements of Consideration:

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[1]Letter from Chairman Meserve to Representative Sonny Callahan dated February 11, 2002.

[2]Letter from Chairman Meserve to Alan H. Maurer, M.D., Society of Nuclear Medicine dated February 11, 2002.

"During the 2-year transition period, NRC staff and the Advisory Committee on the Medical Use of Isotopes (ACMUI) will interact with stakeholders in the medical community to develop alternative approaches to address training and experience. As experience is gained by both the NRC and licensees, the Commission remains open to future rule changes. However, if acceptable alternatives cannot be developed and implemented during the 2-year transition period, then Subpart J will be deleted after the transition period, and licensees would have to meet the requirements in Subparts B and D-H."

Finally, as required in SRM-M020219 and addressed following the staff's briefing of the Commission's technical assistants, the staff should provide the Commission options for resolving the training and experience concerns raised by the ACMUI members. I would favor extending the due date on SRM-M020219 from 3/22/02 to six months after publication of the final rule. The staff should provide those options in a Commission paper before the revised final rule becomes effective (i.e., within six months after publication of the final rule). Such a schedule would allow time for adequate Commission deliberation on the recommended changes, provide for public comment on any proposed changes, resolve the training and experience issue, and implement any final changes within the 2-year transition period.

electronic dosimeter) by each specified visitor. The Commission does not intend to require monitoring and recording of individual doses to visitors of hospitalized radiation patients. The NRC evaluated the costs associated with monitoring doses to visitors versus the benefits derived and determined that, at these low doses, monitoring is not justified. However, this does not preclude the licensee from monitoring and recording doses to visitors.

The NRC also did not grant request (4) of the petition that licensees be required to instruct visitors about radiation safety. We believe that licensees should have flexibility in determining how they will effectively limit radiation exposure of the visitors to levels that are as low as is reasonably achievable.

This completes action on PRM-20-24.

PRM-35-16

On January 11, 2001, the NRC docketed a January 3, 2001, letter from Donald A. Podoloff, MD, of the American College of Nuclear Physicians, and Jonathan M. Links, PhD, of the Society of Nuclear Medicine, to the Office of the Secretary, as a petition for rulemaking under 10 CFR 2.802 (PRM-35-16). The petitioners requested that the Commission: rescind its approval of the NRC staff's proposed revision to 10 CFR part 35, "Medical Use of Byproduct Material"; revoke all of 10 CFR part 35, except for specifically identified requirements; and institute a new rulemaking proceeding to adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine that reflects the discipline's "unparalleled and undisputed safety record."

The petitioners believe that the requested changes would benefit the public in two ways. First, substantial requirements for physicians' education, training, and experience, and appropriate evidence of mastery by testing, would improve the knowledge and abilities of physicians offering diagnostic nuclear medicine. Second, costs to the health care system would decrease without any decrease in safety.

The NRC denied the petition because:

(1) The Commission approved the final rule addressing the issues raised in the petition after an extensive rulemaking process that provided an unprecedented level of enhanced stakeholder and public participation;

(2) The Commission believed that the ACNP/SNM had many opportunities to present their concerns and suggestions as part of that process and did so; and

(3) The petition did not appear to present any significant new information or recommendations that the Commission has not already considered.

This completes action on PRM-35-16.

III. Summary of Public Comments and Responses to Comments

This section summarizes the written and oral comments that we received on the proposed rule and provides responses to these comments. Part I contain a list of the acronyms used in this section. Part II discusses general issues that were considered during the rulemaking. Part III discusses specific comments on the proposed rule.

~~D through H when the rule becomes effective on [insert date 6 months from publication of the final rule]. All commercial nuclear pharmacy licensees (10 CFR 32.72 licensees) will have to comply with the new training and experience requirements for ANPs in §§ 35.55 and 35.59.~~

The NRC believes that Subpart J should be retained for a 2-year transition period as stated in the proposed rule (63 FR 43516; August 13, 1998). The issue of recognition of medical and other specialty boards was discussed during an ACMUI briefing of the Commission on February 19, 2002. In that meeting, two committee members expressed concern that some boards did not qualify for recognition and may not be ready for recognition within 6 months after publication of the final rule. Therefore, implementation of the new Part 35, without Subpart J, could disrupt the current license authorization process for new medical personnel, and might cause shortages of authorized medical personnel, because many license authorizations are granted based on recognition of board certification. The Commission has considered this matter, and decided to retain the current training requirements in Subpart J for a 2-year period after publication of the final rule, as stated in the proposed rule published on August 13, 1998. As stated in Section IX, Implementation, during that 2-year period, licensees will have the option of meeting either the requirements of Subpart J or the requirements in Subparts B and D-H. The NRC states that licensees will have the option of complying with either Subpart J or Subparts B and D-H, and that Subpart J will be deleted after the 2-year period.

The training and experience requirements in Subparts B and D through H of the final rule provide alternative pathways for individuals who are not board certified, i.e., the rule specifies the total number of hours of training and experience needed to become an AMP, ANP, AU, or RSO. This was done because we do not believe that we should require that individuals

granted based on recognition of board certification. The Commission has considered this matter, and decided to retain the current training requirements in Subpart J for a 2-year period after publication of the final rule, as stated in the proposed rule published on August 13, 1998. As stated in Section IX, Implementation, during that 2-year period, licensees will have the option of meeting either the requirements of Subpart J or the requirements in Subparts B and D-H. The NRC states that licensees will have the option of complying with either Subpart J or Subparts B and D-H, and that Subpart J will be deleted after the 2-year period.

Individuals who have status as AUs, AMPs, ANPs, and RSOs at the time the rule becomes effective will be "grandfathered" under § 35.57, and will not have to satisfy the new training and experience requirements. For additional information on the "deemed status" of individuals when the final rule becomes effective refer to the general discussion of the training and experience requirements at the beginning of this section.

Issue 2: Why were the lists of certifying medical boards in Subpart J of the current Part 35 not updated during the rulemaking to include other medical specialty boards and other subspecialties?

Comment. Several commenters noted that there are other medical specialty boards and other subspecialties that should be added to the lists of certifying boards in Subpart J.

Response. The suggested updates were not made in the final rule because Subpart J ~~was~~ will be deleted 2 years after publication of the final rule and there are no lists of certifying specialty boards in the new training and experience requirements in Subparts B and D through

Section 35.690, Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, is a new section. This section contains the training and experience requirements for an AU of teletherapy, remote afterloader, and gamma stereotactic radiosurgery units. The current section, § 35.960, Training for teletherapy, was expanded to include the training for AUs of remote afterloaders and gamma stereotactic radiosurgery units because requirements for gamma stereotactic radiosurgery units and remote afterloader units have been codified in the revised Part 35. Two changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the SUPPLEMENTARY INFORMATION section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after publication of the final rule, this section will replace the current requirements in § 35.960, Training for use of therapeutic medical devices.

~~Subpart J, Training and Experience Requirements, was deleted. The revised training and experience requirements are in Subparts B and D through H. A detailed discussion of the changes to the training and experience requirements is in Section III of the SUPPLEMENTARY INFORMATION section.~~

~~§ 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.~~

Subpart J, Training and Experience Requirements, is in the current Part 35 and will be retained for 2 years. Licensees will have the option to comply with the training and experience requirements in this subpart or in Subparts B and D-H until 2 years after the final rule is published in the Federal Register. At that time, this subpart will be deleted. A more detailed discussion of the Commission's changes to the training and experience requirements is in Section III of the SUPPLEMENTARY INFORMATION section of this document. The schedule for implementation of the training and experience requirements is in Section IX of the SUPPLEMENTARY INFORMATION section of this document.

Section 35.900, Radiation Safety Officer, is in the current Part 35. Two changes have been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist; and § 35.24, Authority and responsibilities for the radiation protection program. This section will be deleted 2 years after the final rule is published in the Federal Register at which time licensees will be required to comply with the training and experience requirements in the new § 35.50, Training for Radiation Safety Officer. Section IX of the SUPPLEMENTARY INFORMATION section of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.901, Training for experienced Radiation Safety Officer, was deleted in its entirety, and the requirements of this section have been moved to the § 35.57.

REQUEST REPLY BY: 4/11

UNITED STATES
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OFFICE OF THE
SECRETARY

March 28, 2002

Approved subject to the attached comments.

Jeffrey S. Merrifield, 4/3/02

COMSECY-02-0014

MEMORANDUM TO: Chairman Meserve
Commissioner Dicus
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Commissioner McGaffigan
Commissioner Merrifield

FROM: Annette L. Vietti-Cook, Secretary

SUBJECT: RE-AFFIRMATION OF THE FINAL RULE ON PART 35 -- MEDICAL USE OF BYPRODUCT MATERIAL

The final rule on Medical Use of Byproduct Material (Part 35) was affirmed by the Commission on October 23, 2000. Publication of the final rule has been delayed based on direction from Congress not to implement or enforce certain parts of the rule until after the NRC submitted a report to Congress explaining why the regulatory burden associated with the rule could not be reduced further without adversely affecting the public health and safety. The NRC submitted the report to Congress on February 11, 2002. Subsequently, as briefed to the Technical Assistants, the staff is recommending that the final rule be revised to include Subpart J, Training and Experience Requirements, as was included in the proposed rule.

The pages of the *Federal Register* notice (FRN) which contain the major changes to the Statement of Consideration and the Final Rule are attached. The remaining pages of the FRN are available in SECY and will be provided if requested. Additional conforming changes have been made throughout the FRN.

The Commission is requested to vote on the attached revision to Part 35. Once all votes are received, an affirmation session will be scheduled for the Commission to re-affirm the final rule prior to publication.

Attachment: Changes to the FRN on the Final Rule on Part 35

cc: EDO
OGC
CFO
OCA
OIG
OPA

Comments from Commissioner Merrifield on COMSECY-02-0014:

I approve the staff recommendation to modify the final Part 35 rule to allow a two year transition period for training and experience requirements. There are two editorial corrections to be made to the package.

1. On page 44, the last sentence of the new paragraph (i.e., "The NRC states that ...") should be deleted. It is redundant to the preceding sentence.

2. The same paragraph found on page 44 is also located on page 323 (end on page 324). Again the last sentence should be deleted.